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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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UNITED STATES DEPARTMENT OF ENERGY
1000 INDEPENDENCE AVENUE, S.W.
ATTN: GC-62 (CHI), MS 6F-067
WASHINGTON, DC 20585-0162

EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/721,996

Applicant(s)

SOMERVILLE ET AL.

Examiner

Ganapathirama Raghu

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 4-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/27/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are pending in this application and claims 1-3, 8-9 and 12-14 are now under consideration for examination. Claims 4-11 and 15-17 are withdrawn as they are drawn to non-elected inventions.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-14 and SEQ ID NO: 1 for prosecution in their response dated 21 July 2006 is acknowledged. The traversal is on the grounds there would not be serious burden on the examiner to examine both groups I and II together and therefore restriction between groups be withdrawn and have requested for examination of all the claims.

Applicants' arguments have been considered, and at the outset the claims are regrouped as follows:

Group I: Claims 1-3, 8, 9, 12-14, directed to an isolated and purified gene encoding an isoxaben cellulose synthase gene with a specified nucleic acid sequence comprising an amino acid sequence of SEQ ID NO: 5 or a fragment thereof at least 60 residues including residues 942, wherein there is a first amino acid substitution at residue 998 of SEQ ID NO: 5, classified in class 435, subclass 209.

Group II: Claims 1, 4-5, 10-11, directed to an isolated and purified gene encoding an isoxaben cellulose synthase gene with a specified nucleic acid sequence comprising an amino acid sequence of SEQ ID NO: 5 or a fragment thereof at least 60 residues including residues 942 and 998, wherein there is a first amino acid substitution at residue 942 of SEQ ID NO: 5, classified in class 435, subclass 209.

Art Unit: 1652

Group III: Claims 1, 6-7, 15-17, directed to an isolated and purified gene encoding an isoxaben cellulose synthase gene with a specified nucleic acid sequence comprising an amino acid sequence of SEQ ID NO: 5 or a fragment thereof at least 60 residues including residues 998, wherein there is a first amino acid substitution at residue 942 and a second amino acid substitution at amino acid residue 998 of SEQ ID NO: 5, classified in class 435, subclass 209.

However examiner respectfully disagrees with applicants' argument "there would not be serious burden on the examiner to examine all the claims and therefore restriction between groups should be withdrawn" for following reasons. Even though the groups are all mutants of the same gene, they are all structurally distinct, i.e., mutations of different positions and therefore have to be searched independently as mutations at one position does not teach or make obvious mutations at other positions. Furthermore, the polynucleotide encoding an isoxaben resistant cellulose synthase when given the broadest interpretation encompasses molecules which are claimed in terms of variants and mutants from any source, since the base claim 1 is very broad without any structural limitations, searching structurally distinct molecules of the polynucleotides of all the groups and the corresponding polypeptides are not coextensive and involves search of different databases and non-patent literature, as prior to the concomitant isolation and expression of the sequence of interest there may be scientific journal articles devoted solely to the polypeptides which would not have described the polynucleotide and moreover the polypeptides may have been isolated by biochemical means as opposed to the expression of the polypeptide through recombinant methods and this would impose a serious search burden and analysis of results. Therefore, for the above cited reasons searching of all

Art Unit: 1652

claims is a serious search burden and contrary to applicants' argument, the requirement is still deemed proper. Therefore, Group I claims pertaining to the elected sequence of SEQ ID NO: 1 are under consideration. Claims 4-7, 10-11 and 15-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

This application is a continuation-in-part of, and seeks priority to, application No. 09/686,234 filed on Oct. 11, 2000, which in turn was submitted in reference to, and sought priority of, Provisional Application No. 60/159,369 filed on October 14, 1999. However, examiner notes that the first disclosure of SEQ ID NO: 1 was presented in the application 09/686,234 filed on Oct. 11, 2000 and therefore the priority date for SEQ ID NO: 1 and claims pertaining to said sequence is Oct. 11, 2000.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 27 Feb. 2004 is filed after the mailing date of the application on 26 Nov. 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawings are accepted for examination purposes only.

Claim Objections

Claims 2 and 8 are objected to because of the following informalities:

Claim 2 and 8 are duplicates as SEQ ID NOs: 1 and 4 are degenerate variants of each other. Applicant is advised that should claim 2 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, 3, 9 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to an isolated mutant gene encoding an isoxaben resistant cellulose synthase with a specified nucleic acid sequence. claims Claim 1 is rejected under this section 35 U.S.C. 112, because the claims are directed to a genus of polypeptides with no support in the specification for the structural details associated with the function i.e., isoxaben resistant cellulose synthase activity. No description of identifying characteristics of all of the sequences including variants, mutants and

Art Unit: 1652

recombinants of an isolated polynucleotide from any source and encoding a polypeptide having isoxaben resistant cellulose synthase activity has been provided by the applicants in the specification. No information, beyond the characterization of an isolated mutant gene encoding a isoxaben resistant cellulose synthase comprising the nucleotide of SEQ ID NO: 1 or SEQ ID NOs: 2 and 3, and encoding a polypeptide comprising a sequence of SEQ ID NO: 5 having the isoxaben resistant cellulose synthase activity from *Arabidopsis* has been provided by the applicants, which would indicate that they had possession of the claimed genus all of the sequences including variants, mutants and recombinants of an isolated polynucleotide from any source and encoding a polypeptide having isoxaben resistant cellulose synthase activity. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Claims 3, 9 and 12-14 recite a genus of polynucleotides encoding a isoxaben resistant cellulose synthase and comprising 20 nucleotides or (60 amino residues) of SEQ ID NOs: 1 or 4 including residues 3160-3162. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the

Art Unit: 1652

genus, one must describe a sufficient variety of species to reflect the variation within the genus. Satisfactory disclosure of a representative number depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus, which embraces widely variant species, cannot be achieved by disclosing only one species within the genus. In the instant case the claimed genera of Claims 3, 9 and 12-14 includes species wherein the nucleic acid sequence comprises at least 20 contiguous nucleotides of SEQ ID NO: 1 including 3160-3162 of SEQ ID NO: 1 (claim 3), the nucleic acid sequence comprises at least 20 contiguous nucleotides of SEQ ID NO: 4 including 3160-3162 of SEQ ID NO: 4 (claim 9), and polypeptide comprising the amino acid sequence of SEQ ID NO: 5 or a fragment thereof at least 60 residues in length including residue 998, wherein the first amino acid substitution is at residue 998-the glycine residue of wild-type substituted to aspartic acid (claims 12-14). The recited structural feature, i. e., 20 nucleotides of SEQ ID NO: 1 or 4 is insufficient to provide the claimed nucleic acid with the recited function of encoding an isoxaben resistant cellulose synthase. As such the recited structure does not correlate with the recited function and neither the description of the structure and function of SEQ ID NO: 1 or 4 nor the disclosure based solely on structural features present in all members of the genus is sufficient to be representative of the attributes and features of the entire genus. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Art Unit: 1652

Claims 1, 3, 9 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated mutant gene encoding a isoxaben resistant cellulose synthase comprising the nucleotide of SEQ ID NO: 1, and encoding a polypeptide comprising a sequence of SEQ ID NO: 5 having the isoxaben resistant cellulose synthase activity from *Arabidopsis*, does not reasonably provide enablement for any polynucleotide encoding a isoxaben resistant cellulose synthase from any source including variants, mutants and recombinants or any gene encoding an isoxaben resistant cellulose synthase comprising at least 60 amino acids of SEQ ID NO: 5 or said gene comprising at least 20 nucleotides of SEQ ID NO: 1 including nucleotides 3160-3162 of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with the claim.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1, 3, 9 and 12-14 are so broad as to encompass any polynucleotide encoding an isoxaben resistant cellulose synthase from any source including variants, mutants and recombinants (claim 1) or any gene encoding an isoxaben resistant cellulose synthase comprising at least 60 amino acids of SEQ ID NO: 5 (claims 12-14) or said gene comprising at least 20 nucleotides of SEQ ID NO: 1 or 4 including nucleotides 3160-

Art Unit: 1652

3162 of SEQ ID NO: 1 or 4 (claims 3 and 9). The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires knowledge and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to an isolated mutant gene encoding a isoxaben resistant cellulose synthase comprising the nucleotide of SEQ ID NOs: 1-3, and encoding a polypeptide comprising a sequence of SEQ ID NO: 5 having the isoxaben resistant cellulose synthase activity from *Arabidopsis*, but provides no guidance with regard to the making of variants and mutants from any source or with regard to other uses. In view of the great breadth of the claims, amount of experimentation required to make the claimed polypeptides the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions or deletions.

The specification does not support the broad scope of the claims for any polynucleotide encoding a isoxaben resistant cellulose synthase from any source including variants, mutants and recombinants, because the specification does not establish: (A) regions of the protein/polynucleotide structure which may be modified without affecting the activity of encoded isoxaben resistant cellulose synthase activity; (B) the general tolerance of the polypeptide and the polynucleotide encoding isoxaben resistant cellulose synthase activity to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue or the respective codon in the polynucleotide with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claim broadly including polypeptides with an enormous number of modifications. The scope of the claim must bear a reasonable correlation with the scope

Art Unit: 1652

of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotides encoding a polypeptide of isoxaben resistant cellulose synthase activity and having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8 and 12-14 is rejected under 35 U.S.C. 102(b) as being anticipated by Heim et al., (Plant Physiol., 1990, Vol. 92: 858-861) and as evidenced by Scheible et al., (PNAS 2001, Vol. 98 (18): 10079-10084) when given the broadest interpretation. Claim 1 is directed to an isolated mutant gene encoding a isoxaben resistant cellulose synthase with a specified nucleic acid gene sequence.

Heim et al., (*supra*) disclose the gene locus designated a *Ixr A* in *Arabidopsis thaliana*, that confers resistance to the herbicide isoxaben. While the reference cited above is silent on the specified nucleic acid sequence, since the loci has been physically identified and isolated, the mutant gene encoding a isoxaben resistant cellulose synthase is inherently represented and present within the isolated gene loci. This is evidenced by later work presented in reference of Scheible et al., (*supra*), wherein the mutant cellulose

Art Unit: 1652

synthase gene was isolated from said loci and shown to comprise a point mutation at position 3161 G→A (SEQ ID NO: 1) and the corresponding change in polypeptide position 998 Gly→Asp (Column 1, second paragraph, Results section, page 10081). Therefore the reference of Heim et al., anticipates the claims 1-3, 8 and 12-14 as written.

Conclusion


None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652

Aug. 01, 2006.


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1652